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| ART UNIT | PAPER NUMBER |
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| 1637 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/001,843 | SALCEDA ET AL. | |
| | Examiner | Art Unit | |
| | Teresa E Strzelecka | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6,9-14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *20022003* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I (claims 1-5, 7, 8, 15 (in part) and 17 (in part), SEQ ID NO: 19 and 20) in Paper No. 14112003 is acknowledged. The traversal is on the ground(s) that:

A) A search for prior art relating to an elected nucleic acid, polypeptide or antibody would also reveal any references teaching uses for the nucleic acid, polypeptide or antibody.

B) Ten sequences should be allowed for each application according to MPEP.

This is not found persuasive because, even though Applicants are somewhat correct in arguing that search for prior art (excluding sequence databases) relating to a nucleic acid might reveal references teaching uses of nucleic acid, polypeptide or antibody, Applicants claim nucleic acids with specific sequences, identified by SEQ ID NOs. In this case, sequence databases are searched for homologous nucleic acid sequences. As Applicants are well aware, search for a nucleic acid sequence (composed of nucleotides) would not identify a polypeptide, which consists of amino acids, and the sequence of which would have to be searched for in protein sequence databases, nor would it identify an antibody, the amino acid sequence of which is totally unrelated to a polypeptide for which it might be specific. Therefore, considering nucleic acids with polypeptides and antibodies requires three different types of searches which are not coextensive, and thus would place an undue burden on the examiner.

Regarding B), the argument is not found persuasive because MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to

represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Therefore, since each of the SEQ ID NOs represents a distinct invention, examination of ten distinct inventions would place an undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6, 9-14 and 16 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14112003.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*4.* Claims 1-5, 7, 8, 15 and 17 will be considered to the degree that they read on SEQ ID NO: 19 and 20.

***Information Disclosure Statement***

5. The information disclosure statement (IDS) submitted on February 20, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-5, 7, 8, 15 and 17 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The current claims are drawn to a an isolated nucleic acid molecule comprising SEQ ID NO: 19 or 20, a nucleic acid which selectively hybridizes to the nucleic acid comprising SEQ ID NO: 19 or 20 or a nucleic acid having at least 60% sequence identity to SEQ ID NO: 19 or 20.

**Credible Utility**

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the nucleic acids. The only cited utilities identified by the examiner are as probes and primers (pages 40-44), protein expression (pages 44-53), production of transgenic animals and cells (pages 88-92), diagnosis of breast cancer (pages 95-102), detection of non-cancerous breast disease (page 102-103), identifying breast tissue (page 103-104). These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the nucleic acid comprising SEQ ID NO: 19 or 20. No well established utilities for this specific nucleic acid are identified in either the specification.

**Substantial utility**

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the specification. Here, as provided by the specification, nucleic acid with SEQ ID NO: 19 or 20 has been identified by data mining of sequences in the Incyte Genomics LIFESEQ® database using CLASP software (page 116), and SEQ ID NO: 19 or 20 have not been assigned to any of the CLASP levels. It is not clear what was the source of the nucleic acid (cell culture or tumor) and what was the level of expression of SEQ ID NO: 19 or 20

in cancer vs. normal cells, therefore it is not clear how a nucleic acid molecule comprising SEQ ID NO: 19 or 20 could be used for detection of breast malignancies, for example.

As noted in the utility guidelines, methods of treating unspecified diseases, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities (see page 6 of the Utility guideline training materials). In the instant case, additional research would be necessary to establish substantial utility of a nucleic acid comprising SEQ ID NO: 19 or 20.

In order for a polynucleotide to be useful for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide and a disease or disorder. The presence of a polynucleotide in breast tissue cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polypeptide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only

serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

**Specific Utility**

In the current case, even if the substantial utility argument above were found unpersuasive, then the substantial utility of the nucleic acid comprising SEQ ID NO: 19 or 20 is, at best, a relationship to an association with breast tissue. This utility is not specific because there are a lot of different nucleic acids expressed in breast tissue, 115 of them provided by Applicants. Thus, the presence of the nucleic acids in breast tissue, which has not been documented for SEQ ID NO: 19 or 20, does not provide a specific utility because there is no direct or even indirect connection made between any particular utility and the nucleic acid comprising SEQ ID NO: 19 or 20. Therefore, even though Applicants claim that the nucleic acids could be used in detection and monitoring of breast cancer, no specific association between the breast cancer and SEQ ID NO: 19 or 20 has been provided, and thus, no specific utility for SEQ ID NO: 19 or 20.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5, 7, 8 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claims 1-5, 7, 8 and 15 are drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 19 or 20, a nucleic acid which selectively hybridizes to the nucleic acid comprising SEQ ID NO: 19 or 20 or a nucleic acid having at least 60% sequence identity to SEQ ID NO: 19 or 20. Applicants assert that nucleic acids with SEQ ID NO: 1-115 can be used for diagnosis of breast cancer (pages 95-102), detection of non-cancerous breast disease (page 102-103), identifying breast tissue (page 103-104). However, as will be further discussed, there is no support in the specification and prior art for the asserted use of the nucleic acid with SEQ ID NO: 19 or 20. The invention is a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Working Examples

The specification has no working examples of using a nucleic acid with SEQ ID NO: 19 or 20 for detection of breast cancer, non-cancerous breast disease or in identifying breast tissue.

Guidance in the Specification.

The specification provides no evidence that the disclosed nucleic acid sequences can be in fact used for detection of breast cancer, non-cancerous breast disease or in identifying breast tissue. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely discloses that nucleic acids with SEQ ID NO: 19 or 20 have been identified by data mining of sequences in the Incyte Genomics LIFESEQ® database using CLASP software (page 116), and SEQ ID NO: 19 or 20 were not assigned to any of the CLASP classes. No further explanations were provided in the specification regarding SEQ ID NO: 19 or 20. It is not clear what was the source of the nucleic acid (cell culture or tumor) and what was the level of expression of SEQ ID NO: 19 or 20 in cancer vs. normal cells, therefore it is not clear how a nucleic acid molecule comprising SEQ ID NO: 19 or 20 could be used for detection of breast malignancies, for example.

The unpredictability of the art and the state of the prior art

Applicants did not show what type of cells nucleic acids with SEQ ID NO: 19 or 20 were obtained from, i.e., whether these cells were from tissue culture or primary tumors. At the time the invention was made, it was known in the prior art that observations of genetic status in cancer cell lines are frequently not observable in primary tumor tissues. For example, Sidransky *et al.* (US 5856094) teach that although the rate of a homozygous deletion of P16 ranged from 40-60% of breast cancer cell lines, neither homozygous deletions nor point mutations are typically observed in primary breast carcinomas (Col. 2, lines 9-14). The suitability of cell lines in

general as models for primary tumors is also questioned in the prior art. For example, Dermer (Bio/Technology, Vol. 12, March 1994, p. 320) teaches that "[w]hen a normal or malignant body cell survives a crisis period and adapts to immortal life in culture, it takes an evolutionary-type step that enables the new cell line to thrive in its artificial environment...Yet normal or malignant cells in vivo are not like that. This means that cell lines are really a new life form on Earth, neither human nor animal. Evidence of the contradictions between life on the bottom of the lab dish and in the body has been in the scientific literature for more than 30 years, evidence that has been systematically ignored by the cancer establishment (first column)."

Therefore, if the cells considered were cell culture cells, then it is even more problematic if SEQ ID NO: 19 or 20 could be used for detection of breast tumors from patients' tissues.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to enable using of nucleic acids with SEQ ID NO: 19 or 20 for the detection of breast malignancies or breast tissue. A person of skill in the art would have to perform detection studies of SEQ ID NO: 19 or 20 in normal and malignant breast tissues from cell culture and patients' samples, as well as in cells from unrelated tissues, to determine whether there is a difference in the expression levels of SEQ ID NO: 19 or 20 in all of these types of cells, and association of SEQ ID NO: 19 or 20 with breast malignancies. Significance of the increased expression levels needs to be established, as there are usually variations in tissues obtained from different individuals, therefore studies involving statistically significant numbers of patients would also need to be performed.

Conclusion

Given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example it is the position of the examiner that it would require undue experimentation for one of skill in the art to use the claimed nucleic acids for breast malignancies detection.

10. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claim 17 is drawn to a vaccine comprising a nucleic acid of SEQ ID NO: 19 or 20. However, as will be further discussed, there is no support in the specification and prior art for the asserted use of the nucleic acid with SEQ ID NO: 19 or 20 as a vaccine. The invention is a class

of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Working Examples

The specification has no working examples of using a nucleic acid with SEQ ID NO: 19 or 20 as a vaccine for cancer therapy, for example.

Guidance in the Specification.

The specification provides no evidence that the disclosed nucleic acid sequences can be in fact used as a vaccine for cancer therapy. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely discloses that nucleic acids with SEQ ID NO: 19 or 20 have been identified by data mining of sequences in the Incyte Genomics LIFESEQ® database using CLASP software (page 116), and SEQ ID NO: 19 or 20 were not assigned to any of the clasp classes. No further explanations were provided in the specification regarding SEQ ID NO: 19 or 20, or a polypeptide encoded by it.

The unpredictability of the art and the state of the prior art

Applicants did not show any evidence that a vaccination of an animal or a human with a nucleic acid comprising SEQ ID NO: 19 or 20 produces antigenic response. At present, the field of DNA vaccines is still developing and therefore unpredictable, as indicated by two very recent reviews. For example, Leitner et al. (Curr. Pharm. Design, vol. 7, pp. 1641-1667, 2001), several components of the DNA vaccination process need to be further evaluated. They include: 1) better understanding of the parameters which determine the outcome of DNA vaccination (page 1643, third paragraph), 2) effectiveness of full-length genes vs. minigenes (page 1644, firs

paragraph), 3) better understanding of transport mechanisms between various compartments within cells (page 1645, fourth paragraph), 4) role of the mode of injection in the effectiveness of the immunization process (page 1648, paragraphs 2-5), 5) safety of different immunity-enhancing adjuvants, such as CpG DNA (page 1660, paragraphs 4-6).

Donnelly et al. (Int. J. Parasitology, vol. 33, pp. 457-467, 2003) reviews progress in DNA vaccines. They point to the fact that even though some DNA vaccines elicit immune response, the response is lower than the one induced by a protein, possibly requiring high doses of DNA (page 458, fifth paragraph). In addition, some DNA vaccines fail to elicit significant CTL response, while others do (page 458, third paragraph). Even though presentation by dendritic cells seems promising, "improvements to this technology will be needed to provide the flexibility to increase DNA doses to the level required to induce strong immune responses in humans" (page 460, second paragraph). Donnely et al. conclude that better understanding of mechanisms of DNA delivery and immune responses are necessary for development of DNA vaccine approaches, but as new methods come into use, more technical challenges will emerge (page 461, last paragraph).

Therefore, the field of DNA vaccines is still in the stage of initial development, where basic mechanisms of immune response to the DNA need to be evaluated, and strategies for effective design of vaccines based on molecular interactions need to be developed. At a present time, which is slightly over two years after the filing date of the current application, the field of DNA vaccines is still highly unpredictable.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to enable using of nucleic acids with SEQ ID NO: 19 or 20 as an anti-tumor vaccine. A person of skill in the art would have to perform vaccination of animals to determine the level, if any, of elicited immune response. The different methods of DNA delivery to cells, as well as various adjuvants, would need to be tested for their enhancing effects. The animals would need to be evaluated for the effectiveness of the vaccine in protection against tumors and in therapy of tumors. The same experiments would need to be performed in humans, since the animal models are not predictive of the outcome in humans, as indicated by Poland et al. (BMJ, vol. 324, pp. 1315-1319, 2002; see page 1315, fourth paragraph).

Conclusion

Given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example it is the position of the examiner that it would require undue experimentation for one of skill in the art to use the claimed nucleic acids as a vaccine.

11. Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5, 7 and 8 are drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 19 or 20, a nucleic acid which selectively hybridizes to the nucleic acid comprising SEQ ID NO: 19 or 20 or a nucleic acid having at least 60% sequence identity to SEQ ID NO: 19 or 20.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID No: 19 or 20. Thus, applicant has express possession of only two particular nucleic acids, in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. No written description of alleles, of upstream or downstream regions containing additional sequence has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the SEQ ID NO: 19 or 20 lack any specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for two specific SEQ ID NO, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to "a nucleic acid that selectively hybridizes to the nucleic acid comprising SEQ ID NO: 19 or 20", for example.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID NO: 19 or 20. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 2, 4, 5, 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Salceda et al. (US 2002/0037250).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Salceda et al. teach sequences with SEQ ID NO: 17 (page 1, [0007], [0009]; page 5, [0055]; page 16, [0169]). SEQ ID NO: 17 (391 bp) is 83.6% identical to SEQ ID NO: 19, with bp 1-391 93.9% identical to bp 1-408 of SEQ ID NO: 19 (see sequence alignment).

Therefore, sequence with SEQ ID NO: 17 is at least 60% identical to SEQ ID NO: 19 and will also hybridize specifically to SEQ ID NO: 19. In addition, SEQ ID NO: 17 is 29.4% identical to SEQ ID NO: 20, with bp 1-391 93.6% identical to bp 747-1154 of SEQ ID NO: 20 (see sequence alignment). Therefore, sequence with SEQ ID NO: 17 will hybridize specifically to SEQ ID NO: 20.

Regarding claim 2, the nucleic acid with SEQ ID NO: 17 is cDNA (page 15, [0163]).

Regarding claims 4 and 5, the nucleic acid with SEQ ID NO: 17 is human DNA (page 15, [0162]; sequence listing, page 31).

Regarding claims 7 and 8, Morris et al. teach vectors and host cells (page 6, [0067]-[0068]; page 7-9).

14. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by GibcoBRL Catalog (p. 7-7, 1993-94).

GibcoBRL catalog teaches a kit with random primers (hexamers), which are suitable for DNA synthesis (page 7.7). Therefore, since any DNA can be amplified with such primers, they can be used to detect the nucleic acid comprising SEQ ID NO: 19 or 20.

***Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 7 and 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of copending Application No. 09/817,318.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the current application is drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence that selectively hybridizes to a nucleic acid comprising SEQ ID NO: 19 or 20, or to a nucleic acid molecule having at least 60% sequence identity to a nucleic acid comprising SEQ ID NO: 19 or 20. Claim 1 of the copending Application No. 09/817,318 is drawn to a nucleic acid comprising SEQ ID NO: 17. Since SEQ ID NO: 17 is 83.6% identical to SEQ ID NO: 19, with bp 1-391 93.9% identical to bp 1-408 of SEQ ID NO: 19 (see sequence alignment) and 29.4% identical to SEQ ID NO: 20, claim 1 of the copending Application No. 09/817,318 anticipates claim 1 of the instant application.

The dependent claims 7 and 8 of the instant application are drawn to the vectors and host cells comprising nucleic acids of claim 1, therefore they are anticipated by claims 3 and 4 of the copending Application No. 09/817,318.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. No claims are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary Benzion will move to the new office on January 22, 2004. His new phone number is (571) 272-0782.

TS
January 20, 2004

JEFFREY FREDMAN
PRIMARY EXAMINER